REMARKS

Claims 17-23 are pending. Claim 17 has been amended to delete the term "prophylaxis". No new matter has been added. Reconsideration is requested.

Claims 17-23 were rejected under 35 USC § 112, first paragraph, as lacking enablement. It is the Examiner's view that the specification does not reasonably provide enablement for "prophylaxis" of respiratory diseases, allergic diseases, asthma, and COPD. The claims have been amended to delete "prophylaxis". Accordingly, withdrawal of the rejection is respectfully requested.

Claims 17-23 were rejected under 35 USC § 103 as being obvious over Goodfellow et al. (US PUB 2004/0214805) in view of Szelenyi et al. This rejection is traversed for the following reasons.

It is the Examiner's view that Goodfellow teaches the treatment of pulmonary diseases with a combination of PDE4 inhibitor and corticosteroid. The document does not mention loteprednol as soft steroid. The document also does not disclose a synergistic anti-inflammatory effect for any of the mentioned combinations of PDE4 and corticosteroid. In contrast, this is clearly disclosed and claimed in the present application. Thus, the important features which distinguish the present invention from the prior art are the synergistic inhibition of inflammation and the use of the soft steroid loteprednol instead of a classical steroid. It is respectfully submitted that the claimed combination is not disclosed or suggested in the cited references and has unexpected advantages that make it patentable over the combination of cited art.

As already mentioned, the synergistic effect of the presently claimed combination is clearly demonstrated in the experimental data of the present application, which analyzes totally different parameters than the specific arthritis models of the prior art document. The experimental data in the present application show the synergistic reduction of granulocyte-macrophage colony stimulating factor (GM-CSF) or tumor necrosis factor (TNF) release from stimulated monocytes as an indicator for the reduction of inflammation. These molecules are important modulators of the

inflammatory component of respiratory diseases such as asthma, COPD or allergic respiratory diseases. Thus, the synergistic effect has been shown using two different models. Both clearly show the improved effect of the combination of loteprednol/DFHO in contrast to the single substances.

An additional advantage that must be considered is that loteprednol is not simply a substance chosen from a list of steroids, but a compound that has the mechanism of action of a soft steroid. These advantages are mentioned in the present specification on pages 2-3. Thus, the combination of loteprednol/DFHO not only provides synergistic anti-inflammatory effects, but at the same time reduced side effects compared to classical steroids.

For all of the above reasons, it is respectfully submitted that the presently pending claims are not obvious from Goodfellow et al. in view of Szelenyi et al. Reconsideration and withdrawal of the rejection are respectfully requested.

All objections and rejections having been addressed, it is respectfully submitted that this application is in condition for allowance, and Notice to that effect is respectfully suggested.

Respectfully submitted,

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